REMARKS/ARGUMENTS

1. Status of the Claims

Claims 1-20 are pending in the application.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afriat et al. (US 6,203,576) in view of Davidson (US 5,180,394). Applicant respectfully traverses the rejection and requests reconsideration.

Claims 1, 5, 10 and 13 have been amended.

2. Changes to the Specification

Although the meaning of UHMWPE in the abstract is clear, the abstract in any event has been expanded to spell out the abbreviation UHMWPE (ultra-high molecular weight polyethylene).

Although the meaning of UHMWPE in the specification is clear, the occurrence of the abbreviation "UHMWPE" (page 4, para 0014, line 5) has been expanded to spell out the abbreviation UHMWPE (ultra-high molecular weight polyethylene).

On page 6, para 0025, line 6 and line 9: tibial insert "36" and tibial platform "36 have the same numbering. The word "tibial insert" has been changed to "tibial platform".

On page 8, para 0034, line 4, "100" has been changed to "101".

The specification is objected to under 37 CFR 1.75(d)(1) and MPEP § 608.01(o) as failing to provide proper antecedent basis for the subject matter of claims 5 and 13. Applicant respectfully contends that paragraph 0018, last sentence supports claims 5 and 13. Additionally, the claims 5 and 13, as part of the specification, also support the claims. Applicant requests withdrawal of this objection.

3. Claim Objections

Claims 1 and 10 are objected to because:

In claim 1, line 9: "component" (second occurrence) should be "insert" to be consistent with the disclosure. Claim 1 has been amended accordingly.

In claim 10, line 2 - -"of the patient"—must be inserted after "in the body" for clarity. Claims 10 has been amended accordingly.

4. Miscellaneous Changes to Claims

Claims 5 and 13 have been amended. In claim 5, the words "of the load bearing surface" have been added after the first occurrence of zirconium oxide. In claim 13, a period has been added to the end of the claim.

5. Obviousness Rejection - Afriat et al. (US 6,203,576) in view of Davidson (US 5,180,394).

The burden of showing a *prima facie* case of obviousness is on the Examiner, who must show evidence beyond merely stating that the claimed invention is obvious in light of the prior art. *See Manual of Patent Examining Procedure* 2144.03; *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966). If the Examiner fails to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). Even if the Examiner properly meets the burden of showing a *prima facie* case of obviousness, the Applicant may still overcome the obviousness rejection through a showing of secondary considerations such as unexpected results, long felt need, failure by others or commercial success. *See Id.* at 17-18.

In order to establish a prima facie case of obviousness, three basic criteria must be met: (1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *Manual of Patent Examining Procedure* § 2142. See also, *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991) (emphasizing that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must

be both found in the prior art, and not based on Applicant's disclosure). It is important to note that all three elements must be shown to establish a prima facie case of obviousness. Thus, if one element is missing, a prima facie case of obviousness does not exist.

a) There is no motivation to combine the cited references

When an obviousness determination is based on multiple prior art references, there must be a showing of some "teaching, suggestion, or reason" to combine the references. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997) (also noting that the "absence of such a suggestion to combine is dispositive in an obviousness determination"). The absence of such a suggestion to combine is dispositive in an obviousness determination. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 886-87, 8 USPQ2d 1468, 1475 (Fed. Cir. 1988). *See In re* Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990) (the PTO erred in rejecting the claimed invention as an obvious combination of the teachings of two prior art references when the prior art provided no teaching suggestion or incentive supporting the combination). The "mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *Manual of Patent Examining Procedure* § 2143.01; see also, *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Finally, although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." *In re Mills*, 916 F.2d 680, 682, USPQ 2d 1430, 1432 (Fed. Cir. 1990).

A prima facie case of obviousness has not been established by the Action because it fails to show any motivation to combine the teachings of Davidson and Afriat et al. Contrary to the assertions of the Action, these references are not sufficient to form a prima facie case of obviousness. Neither the Davidson, nor the Afriat et al. references show any motivation to combine the teachings to achieve Applicant's claimed invention. The sum of the disclosures of the cited references lacks the clear and particular suggestion or motivation to combine the various elements to achieve the present invention. Therefore, taken as a whole, the references cannot form a valid prima facie case of obviousness against the present claims 1 – 20.

Since there is no suggestion in the cited references to combine the teachings of Davidson with Afriat et al., a prima facie case of obviousness has not been established.

(b) There is no reasonable expectation of success that the combination of the teachings of the references would work

The Davidson and Afriat et al. references as a whole, viewed in light of the knowledge of the ordinary artisan at the time of filing, do not assure the artisan of any reasonable expectation of success, even if the artisan were to try and make the invention.

Applicant respectfully points out that the Afriat et al. reference does not contain all the limitations of the claims as discussed below in the next section. Accordingly the combined references therefor can not enable what it does not disclose, and therefore provides no reasonable expectation of success in making the present invention. Applicant therefore respectfully traverses the obviousness rejection.

(c) The prior art references do not teach or suggest all of the claim limitation

The holding in *In re Royka*, 490 F.2d 981 (CCPA 1974) states that all of the claim limitations must be taught or suggested by the prior art. Here, in order for the Afriat et al. reference to form the basis of a rejection under 35 U.S.C. §103(a), it must disclose or suggest, each of the claimed elements of independent claims 1, 10 and 16 (including the independent claims). If an independent claim is nonobvious under 35 U.SA.C 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Independent claim 1 (and dependent claims) requires that "the cam having a diffusion-hardened surface along a portion of the cam for adding strength and wear resistance to the contact zones of the cam." Independent claim 16 (and dependent claims) requires that "the cam having a having diffusion-hardened surface along a portion of its length for adding strength to the impact zones of the cam."

The Action, however, **admits** that the Afriat et al. reference does not disclose a diffusion-hardened surface or coating on a portion of the cam for adding strength and wear resistance to the contact zones of the cam. Moreover, the Action **admits** that Davidson does not specifically disclose diffusion-hardened coating of a cam surface (load-bearing surface) or the inner side of parallel vertical walls connected to the inner sides of posterior condylar portions (non-load bearing surface) of a femoral component of a knee joint prosthesis. Additionally, the Action **admits** that the Afriat et al. reference does not disclose a cam

shaped as a horizontal bar. The Action impermissibly tries to add undisclosed features to independent claims 1 and 16 by concluding that it would have been obvious to one of ordinary skill in the art to add these elements. However, neither reference alone, nor in combination teaches these requirements.

6. Conclusion

Applicant respectfully requests withdrawal of the rejection to claims 1-20 based on the obviousness rejection - Afriat et al. (US 6,203,576) in view of Davidson (US 5,180,394).

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02368US0 from which the undersigned is authorized to draw.

Dated: June 11, 2003

Respectfully submitted,

By Edward D. Steakley

Edward D. Steakley
Registration No.: 47,964
FULBRIGHT & JAWORSKI L.L.P.
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
(713) 651-5423
(713) 651-5246 (Fax)
Attorneys for Applicant

Version With Markings to Show Changes Made

In the Abstract

An orthopedic implant with a diffusion-hardened surface on non-load bearing areas of the implant for interaction with non-load bearing surfaces of a polymeric bio-compatible material, such as UHMWPE (ultra-high molecular weight polyethylene). The orthopedic implant is a posterior stabilized knee prosthetic and system where a coating of oxidized zirconium is formed on the cam of the femoral prosthetic for interaction with the central post of a polymeric tibial insert. The diffusion-hardened surface of the orthopedic implant provides a strengthened cam and reduction in wear in the central post of the polymeric tibial insert.

In the Specification

[0014] In one embodiment of the invention, the prosthetic implant includes one or more load bearing surfaces and one or more non-load bearing surfaces. The load bearing surfaces of the implant are sized and shaped to engage or articulate with the load bearing surfaces of the second prosthetic device. The second prosthetic device is formed from a bio-compatible, organic polymer or polymer-based composite, such as UHMWPE (ultra-high molecular weight polyethylene). A diffusion-hardened surface is employed on the load bearing surfaces and the non-load bearing surface of the prosthetic implant.

[0025] Figures 1 and 2 show a typical knee joint prosthesis as disclosed in the prior art where porous bead or wire mesh zirconium oxide coatings can be applied to the tibial or femoral components of the knee or both. The porous metal bead or wire mesh coating is incorporated to allow stabilization of the implant by in-growth of surrounding tissue into the porous coating. The knee joint includes a femoral component 20 and a tibial component 30 with a tibial [insert] platform 36. The femoral component includes condyles 22 which provide the articulating surface of the femoral component and pegs 24 for affixing the femoral component to the femur. The tibial component 30 includes a tibial base 32 with a peg 34 for mounting the tibial base onto the tibia. A tibial platform 36 is mounted atop the tibial base 32 and is supplied with grooves 38 similar to the shape of the condyles 22. The bottom surfaces of the condyles 26 contact the tibial platform's grooves 38 so that the condyles articulate within these grooves against the tibial platform. While condyles are typically

fabricated of metals, the tibial platform may be made from an organic polymer or a polymer-based composite. The hard metallic condyle surfaces 26 articulate against a relatively softer organic composition. Zirconium oxide or nitride may be employed on the condyles for articulation with the load-bearing surfaces tibial grooves 38.

[0034] As is illustrated in Figure 5, a range of motion for the patient's knee fitted with the knee prosthesis 40 as illustrated with arrows 100, 101. For purposes of reference, the patient's central longitudinal axis 102 of the distal femur 95 is shown rotating in the direction of arrow [100]101. In the flexed position shown, the horizontal bar cam 54 of femoral component 50 registers against the posterior surface 77 of central post 74 of polymeric insert 70. In this position, the central post 74 causes femoral roll back on the tibia articular insert 70. The posterior aspect of the tibia articular surface at 77 provides a lift that is created by generally following the curvature of the femoral component 50 in extension. This will provide a high degree of surface contact, conformity, subsequently providing low contact stress, in extension, where most of gait occurs. The post 74 can have a square or rectangular base that fits snugly with the central opening 57 of the femoral component 50.

In the Claims

1. (once amended) A posterior stabilized knee prosthetic system comprising:

a) a femoral component configured to be surgically implanted into a patient's femur, the femoral component having two condylar portions with a cam extending between the posterior end of the condylar portions, and the cam having a diffusion-hardened surface along a portion of the cam for adding strength and wear resistance to the contact zones of the cam;

b) a tibial component configured to be surgically implanted into a patient's tibia; and

c) a tibial insert having a proximal surface that is shaped to articulate against the femoral component, the insert having a distal surface that fits against the proximal surface of the tibial component, and the tibial [component] insert having a post for engaging the femoral component to provide posterior stabilization.

5. (once amended) The prosthetic system of claim 4, wherein the thickness of the zirconium oxide of the load bearing surface is greater than the thickness of the thickness of the zirconium oxide of the cam.

10. (once amended) A prosthesis for implantation in a patient, comprising:

a prosthesis body for implantation in the body of the patient, the prosthesis body having one or more load bearing surfaces and one or more non-load bearing surfaces,

the load bearing surface on the prosthesis body being sized and shaped to engage or cooperate with a second load bearing surface on another prosthesis portion, said second load bearing surface being formed of an organic polymer or polymer-based composite,

the non-load bearing surface on the prosthesis body being sized and shaped to engage or cooperate with a second non-load bearing surface on another prosthesis portion, said second non-load bearing surface being formed of an organic polymer or polymer-based composite,

a diffusion-hardened coated surface on the bearing surface, and

a diffusion-hardened coated surface on the non-load bearing surface.

13. (once amended) The prosthesis of claim 12, wherein the thickness of the coating of the diffusion-hardened surface of the load bearing surface is greater than the coating of the diffusion-hardened surface of the non-load bearing surface.